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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,913

07/21/2003

Paul D. Grossman

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07/06/2005

KILYK & BOWERSOX, P.L.L.C.
3603 CHAIN BRIDGE ROAD
SUITE E
FAIRFAX, VA 22030

EXAMINER

CHISDES, SARAH J

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,913

Applicant(s)

GROSSMAN ET AL.

Examiner

Sarah J. Chisdes

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-60 is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-13, 15 and 61-63 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 14, 16-19 and 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Information Disclosure Statement***

The Information Disclosure Statement submitted September 29, 2003 has been received and placed of record in the file. An initialed, signed and dated copy of it accompanies this Office action.

The examiner notes that a list of references is included at the beginning of the specification. References may be listed in the specification, but doing so does not constitute a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." If the applicant wishes these references to be formally considered by the examiner they must be included on an information disclosure statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kojima et al (US 2002/0003091 A1). In paragraph 8, lines 5-15, Kojima discloses a capillary array, a means for irradiating with light the samples in the capillaries, and a

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means for detecting the resulting fluorescence, thereby meeting the limitations of a plurality of separation units including an inlet end, outlet end, and an interior portion; and excitation source to direct light into the interior of the separation units, and an emission detection system optically coupled to the interior portion of the separation units. In paragraph 76, lines 3-4, Kojima discloses a black coating on the substrate which holds the capillaries, and further describes in paragraph 83 that the black coating is intended to absorb stray light to reduce noise. This black coating is taken to be a non-fluorescent quencher which comprises a portion of the separation units, thereby meeting all the limitations of claim 1.

Regarding claim 2, Figure 13 of Kojima illustrates a plurality of separation units, with a window (element 4006) disposed on a region of the separation units. The window is taken to be an optical element (it transmits light), and therefore the limitations of claim 2 have been met.

Regarding claims 3 and 4, Figure 13 illustrates a cover (element 4002) for the separation units, and the cover contains a window (element 4006). The window is taken to be an optical element, and therefore the limitations of claims 3 and 4 have been met. Figure 13 also shows that the separation elements do not intersect, thereby meeting the limitation of claim 6.

Claim 5 specifies that the non-fluorescent quencher of claim 1 comprise a pigment. As explained in regard to claim 1, the black coating is understood to be the non-fluorescent quencher. A black coating would inherently comprise a black pigment or a combination of pigments. Therefore the black coating meets the limitation of the non-fluorescent quencher comprising a pigment.

Two reservoirs (elements 412 and 413) can be seen in Figure 8 of Kojima, thereby meeting the limitations of claim 7.

The excitation beam source comprising a laser limitation of claim 8 is met by element 3120 of Figure 12, which is explained to be laser beam source in paragraph 68, lines 5-6.

In regard to claims 11 and 12, it can be seen in Figure 13 that the capillaries are parallel to each other, which provides that the sidewalls of the capillaries are parallel to each other, and that a light path is provided (element 4011), also seen in Figure 12, that extends through the parallel portions of the sidewalls of the capillaries, thereby meeting the limitations of claims 11 and 12.

Claim 13 specifies that the parallel portions through which the light beam extends of claim 12 be transparent. Paragraph 81 of Kojima, specifies "transparent capillaries (4007)" in regard to Figure 13, thereby meeting the specified limitation.

Claims 1, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Li (US 2004/0026252 A1). In paragraph 11, Li provides a plurality of separation lanes, which are preferably an array of capillaries or an array of channels in a micro-fabricated separations device, meeting the limitation of a plurality of separation units including an inlet end, outlet end, and an interior portion; and a detector configured to detect light exiting from the separation lanes, meeting the limitation of an emission detection system optically coupled to the interior portion of the separation units. In paragraph 8, lines 5-6, Li discloses a light source configured to emit light to interact with the sample components, meeting the limitation of an excitation source to direct a beam of light along a path that intersects with the interior portion of each separation unit. Additionally in

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paragraph 63, lines 4-13, Li discloses that "a coating or other absorbing material, such as black paint, is optically associated with an outer surface of each capillary to attenuate the light that reaches the coating," and further describes the coating as not being fluorescent. This non-fluorescent, light absorbing black coating on the capillaries is taken to meet the limitation of a portion of the separation units comprising a non-fluorescent quencher.

Claim 15, which is dependent on claim 1, further specifies that the non-fluorescent quencher is coated on at least one portion of a separation unit. The black coating on the capillaries specified by Li in paragraph 63 and detailed above, thereby meets the limitations of claim 15, and therefore the limitations of claims 1 and 15 are met by Li.

Claims 61-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Pham et al. (US 6,171,780). Regarding claim 61, in column 13, lines 11-19, Pham discloses a multi-well platform (substrate including a plurality of sample containment units disposed in relation to each other of the present application) comprising an optically opaque material (non-fluorescent quencher of the present application) intended to interfere with the transmission of light, and therefore reduce the background light level, thereby meeting the limitations of the claim.

In column 13 lines 26-28, Pham discloses that the optically opaque materials (non-fluorescent quenchers) can be coated onto any surface of the multi-well platform, thereby meeting the limitation of claim 62 that the substrate of claim 61 further comprise a coating containing at least one non-fluorescent quencher.

The limitation of claim 63 that the substrate material be mixed with the non-fluorescent quencher is met by lines 34-39 of column 13 of Pham, where it is described

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that pigments (opaque materials) can be mixed into the substrate material during manufacture of the multi-well plate.

Allowable Subject Matter

Claims 20-60 are allowed.

Claims 9, 10, 14, 16-19, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record, taken alone or in combination fails to disclose a device for the analysis of one or more samples as recited in the combination of elements and steps of claims 9, 10, 14, and 16-19.

Regarding claims 9 and 10, Simpson et al. (US 6,017,434) discloses a device for electrophoresis where separation units are formed in a substrate and laser light is sent transversely through the substrate, and fluorescence is detected from the sample, but does not include non-fluorescent quenchers, or any other molecules or coatings intended to absorb stray light, in the substrate.

Regarding claim 16, Kojima, in Figure 13 provides grooves to partially define the separation units, but does not include a non-fluorescent quencher in the substrate in which the grooves are formed.

Regarding claims 17-19, Yeung (US 5,498,324); in column 12 lines 24-29 teaches that capillaries for a separation device similar to the one of the present invention can be

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coated with an inert, absorbing, non-fluorescing dye, but does not include a reporter dye in the separation units.

Regarding claim 20, from which claims 21-32 depend, and claim 33, from which claims 34-36 depend, the prior art of record taken alone or in combination fails to disclose a device for the analysis of one or more samples as recited in the combination of elements and steps of claims 20 and 33. Simpson discloses a device for electrophoresis where separation units are formed in a substrate, laser light is sent transversely through the substrate, and fluorescence is detected from the sample, but does not include non-fluorescent quenchers, or any other molecules or coatings intended to absorb stray light, in the substrate.

Regarding claim 37, from which claims 38-52 depend, the prior art of record taken alone or in combination fails to disclose a device for the analysis of one or more samples where the sample containment units have one open and one closed end, and at least a portion of the sample containment units comprises a non-fluorescent quencher as recited in combination with the elements and steps of claim 37. Parce et al. (US 6,413,782) discloses a device for the analysis of samples with at least one open end and at least one closed end, but does not include a pigment, dye, light absorber, or non-fluorescent quencher.

Regarding claim 53, from which claims 54-56 depend, and claim 57, from which claims 58-60 depend, the prior art of record taken alone or in combination fails to disclose a method of forming a device where a substrate material and a non-fluorescent quencher are combined to form a substrate with a plurality of adjacently arranged channels or separation units as recited in combination with the elements and steps of

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claims 53 and 57. Kao et al. (US 6,906,797), Blackburn (US 2003/0190608), and Strand et al. (US 2002/0176804) all disclose micro-fluidic devices with channels, but none of them include a pigment, dye, light absorber, or non-fluorescent quencher in the device.

Regarding claim 64, the prior art of record taken alone or in combination fails to disclose or teach a substrate material, either containing or coated with a non-fluorescent quencher, formed into a plurality of sample containment units wherein one or more non-fluorescent quenchers are retained in alternating sample containment units as recited in the combination of elements and steps of claim 64. Oldenberg et al. (US 6,027,695) discloses a multi-well plate with transparent bottoms and light-absorbing non-fluorescing coatings, but does not alternate the placement of the non-fluorescent quenchers within the wells. Cassin et al. (US 5,910,287) utilizes a layer or coating of a cycloolefin to control transmittance and reflectance properties of the multi-well plate, but does not alternate the placement of the light absorbers within the wells.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah J. Chisdes whose telephone number is 571-272-8540. The examiner can normally be reached on 9am -6:30pm Monday through Thursday and 9am -5:30pm on alternate Fridays.

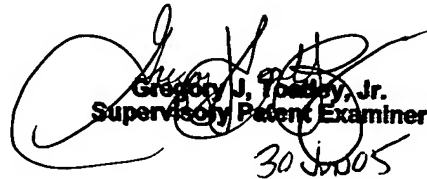
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley Jr. can be reached on 571-272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SJC

S.J. Chisdes, Ph.D.
June 30, 2005


Gregory J. Tolley, Jr.
Supervisory Patent Examiner
30 Jun 05